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10/598,536	09/01/2006	Shigeru Nemoto	KITO15.001APC	6996

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
2ros@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,536	NEMOTO ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-34* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 33 and 34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New claims 33 and 34 are method claims and Applicant has been prosecuting device claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Tanaka (US 2005/0049556) at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference Tanaka (US 2005/0049556) additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claims 1-9 and 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Tanaka (US 2005/0049556). Tachibana discloses the device substantially as claimed including a chemical liquid injection system (Figs. 1-10) including: a liquid syringe (Figs. 2b and 3, syringe is 2) having a piston member (Fig. 2b, 2p) being inserted slidably into a cylinder member filled with a liquid, and a chemical liquid injector (50) having a liquid injection mechanism (52) for relatively moving the cylinder member and the piston member of the liquid syringe exchangeably mounted on the chemical liquid injector to inject the liquid into a patient, said liquid injections mechanism contains a detector for detecting a

pressure applied to the piston member (paragraphs [0071] and [0045] disclose an occlusion detection circuit which detects an increase in pusher force (force applied to the piston)); wherein said liquid syringe further comprises an RFID chip (3) having various types of data including identification data for said liquid syringe recorded thereon (paragraph [0048] discloses that multiple types of data regarding the liquid in the syringe is recorded on the tag including safety data such as the upper and lower limits of flow rate for the drug (paragraph [0007] and [0059]), the RFID chip being mounted on said liquid syringe (Figs. 2b and 3), and said chemical liquid injector further comprises: an RFID reader (Fig. 3, 101) for obtaining the various types of data recorded on the RFID chip; and operation control means for performing a predetermined operation in accordance with at least some of the various types of obtained data (paragraphs [0056]-[0058]), and wherein said operation control means comprises data storing means for storing predetermined check conditions including identification data of usable liquid syringe (Fig. 3, 102; paragraph [0055] discloses that information is read from the tag on the syringe and then this information is stored in 102 such that it can be recalled and compared), data collating means for collating the stored check conditions with the various types of data obtained from said RFID chip (paragraphs [0056] and [0057] disclose that the data is compared by some sort of comparator in order to determine whether an alarm needs to be triggered), data accumulating means for storing the identification data (102; paragraph [0056] discloses that the data is stored so that it can be compared to a set value, which also must be stored in order for it to be compared), and alarm outputting means for outputting a check alarm if the identification

data obtained from said RFID chip is not included in the check conditions as a result of the collation (paragraphs [0056] and [0057] disclose that if the data is determined to be out of range, the buzzer alarm is triggered).

Tachibana, however, does not disclose that the RFID includes the value of pressure resistance of the liquid in the syringe, the inner diameter of the syringe, or that the operation control means is configured to control the liquid injection mechanism such that the detected pressure does not exceed the value of pressure resistance. Tachibana further does not disclose that the detector obtains the pressure by detecting a stress on the piston member and using the inner diameter of the syringe on the RFID to calculate the injection pressure. Tanaka, however, discloses a similar injection system in which a syringe is labeled with a barcode containing identification data of the syringe and contents of the syringe, including the inner diameter of the syringe (paragraphs [0104] and [0091]), and the injector housing having a barcode reader to read the information (paragraph [0104]). Tanaka further discloses that the injector has a load cell to detect the stress on the piston, and that the injection pressure is then calculated based on the detected stress and the inner diameter of the syringe (paragraphs [0078] and [0091]). Tanaka also discloses that the detected and calculated pressures can be used to determine whether or not the injection is being carried out at an unsafe pressure, the injection is halted (paragraphs [0082] and [0083]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana's device such that the RFID tag included information regarding the syringe contents and the inner diameter of the syringe, as well as the load

cell taught by Tanaka, in order to safely and accurately calculate and monitor the injection pressure during the procedure to ensure patient safety, especially since and Tachibana further discloses that the RFID tag can include other such operating data such as the upper and lower limits of the flow rate for the specific liquid in the syringe (paragraphs [007] and [0059]). Furthermore, Tachibana discloses an occlusion detection system which monitors the pressure applied to the piston in order to detect an occlusion during injection. This monitoring of pressure could thus be applied to the monitoring of pressure of the fluid in the syringe and monitoring to make sure that the injection stays within specified safety parameters. In reference to claims 2-9 and 12-14 and 16 see Figs. 1-10 and paragraphs [0048] and [0056]-[0058].

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Tanaka (US 2005/0049556) and further in view of Wilson et al. (US Patent No. 5,573,515). Tachibana in view of Tanaka discloses the device substantially as claimed except for a liquid warmer associated with the injector and the liquid warmer also having an RFID tag reader. Wilson, however, discloses a similar chemical liquid injection system (Fig. 1, for example) as well as a heater to heat the liquid in the syringe (col. 8, lines 17-27). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana in view of Tanaka with the liquid heater to heat the contents of the syringe, as taught by Wilson, in order to provide a device that will administer liquids to

patients that are close to body temperature to ensure that the patient is more comfortable. It would have also been obvious to one of ordinary skill in the art at the time of the invention to have included an RFID tag on the liquid warmer, as Tachibana and Tanaka both disclose identification tags for the syringe and identification systems located on the devices that interact with the syringes in order to automatically carry out the operations associated with the syringe and the information on those ID tags. Including an RFID tag reader on the liquid warmer of Wilson would therefore be a duplication of parts (another RFID tag reader) and it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Tanaka (US 2005/0049556) and further in view of Hickle et al. (US 2003/0074223). Tachibana discloses the device substantially as claimed including: a chemical liquid injection system (Figs. 1-10) including: a liquid syringe (Figs. 2b and 3, syringe is 2) having a piston member (Fig. 2b, 2p) being inserted slidably into a cylinder member filled with a liquid, and a chemical liquid injector (50) having a liquid injection mechanism (52) for relatively moving the cylinder member and the piston member of the liquid syringe exchangeably mounted on the chemical liquid injector to inject the liquid into a patient; wherein said liquid syringe further comprises an RFID chip (3) having various types of data including identification data for said liquid syringe recorded thereon (paragraph [0048] discloses that multiple types of

data regarding the liquid in the syringe is recorded on the tag), the RFID chip being mounted on said liquid syringe (Figs. 2b and 3), and said chemical liquid injector further comprises: an RFID reader (Fig. 3, 101) for obtaining the various types of data recorded on the RFID chip; and operation control means for performing a predetermined operation in accordance with at least some of the various types of obtained data (paragraphs [0056]-[0058]), and wherein said operation control means comprises data storing means for storing predetermined check conditions including identification data of usable liquid syringe (Fig. 3, 102; paragraph [0055] discloses that information is read from the tag on the syringe and then this information is stored in 102 such that it can be recalled and compared), data collating means for collating the stored check conditions with the various types of data obtained from said RFID chip (paragraphs [0056] and [0057] disclose that the data is compared by some sort of comparator in order to determine whether an alarm needs to be triggered), data accumulating means for storing the identification data (102; paragraph [0056] discloses that the data is stored so that it can be compared to a set value, which also must be stored in order for it to be compared), and alarm outputting means for outputting a check alarm if the identification data obtained from said RFID chip is not included in the check conditions as a result of the collation (paragraphs [0056] and [0057] disclose that if the data is determined to be out of range, the buzzer alarm is triggered).

Tachibana, however, does not disclose that the RFID includes the value of pressure resistance of the liquid in the syringe, the inner diameter of the syringe, or that the operation control means is configured to control the liquid injection mechanism such

that the detected pressure does not exceed the value of pressure resistance. Tachibana further does not disclose that the detector obtains the pressure by detecting a stress on the piston member and using the inner diameter of the syringe on the RFID to calculate the injection pressure. Tanaka, however, discloses a similar injection system in which a syringe is labeled with a barcode containing identification data of the syringe and contents of the syringe, including the inner diameter of the syringe (paragraphs [0104] and [0091]), and the injector housing having a barcode reader to read the information (paragraph [0104]). Tanaka further discloses that the injector has a load cell to detect the stress on the piston, and that the injection pressure is then calculated based on the detected stress and the inner diameter of the syringe (paragraphs [0078] and [0091]). Tanaka also discloses that the detected and calculated pressures can be used to determine whether or not the injection is being carried out at an unsafe pressure, the injection is halted (paragraphs [0082] and [0083]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana's device such that the RFID tag included information regarding the syringe contents and the inner diameter of the syringe, as well as the load cell taught by Tanaka, in order to safely and accurately calculate and monitor the injection pressure during the procedure to ensure patient safety, especially since and Tachibana further discloses that the RFID tag can include other such operating data such as the upper and lower limits of the flow rate for the specific liquid in the syringe (paragraphs [007] and [0059]). Furthermore, Tachibana discloses an occlusion detection system which monitors the pressure applied to the piston in order to detect an

occlusion during injection. This monitoring of pressure could thus be applied to the monitoring of pressure of the fluid in the syringe and monitoring to make sure that the injection stays within specified safety parameters. In reference to claims 2-9 and 12-14 and 16 see Figs. 1-10 and paragraphs [0048] and [0056]-[0058].

Tachibana in view of Tanaka, however, does not disclose that the data included in the RFID chip includes the expiration date of the liquid in the syringe, or that the predetermined check conditions include the current date and time. Hickle, however, discloses a similar device which delivers medication and the medication container (a vial) includes an RFID chip on it (paragraph [0046]) which includes data about the fluid filled container such as the expiration date (paragraph [0028]). Hickle further discloses that the device keeps track of the current date and time so that if the reader reads the RFID chip and it says that the drug is expired, the drug will not be delivered and an alarm will be triggered (paragraphs [0030] and [0038] and [0039]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana's RFID chip so that the expiration date of the drug is included and modified the device of Tachibana so that the current date and time are kept track of, so that a safer device is provided and an expired drug is not accidentally administered to the patient which in worst case scenarios could kill the patient. In reference to claims 19-31, see Figs. 1-10 and paragraphs [0048] and [0056]-[0058].

Response to Arguments

Applicant's arguments, see pages 11-14 of Applicant's arguments, filed 1/5/2010, with respect to the rejection(s) of claim(s) s under 1-9, 12-32 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tachibana in view of Tanaka. In reference to Applicant's arguments against the Wilson reference and claims 15 and 17, the examiner has further clarified her position and rejection as seen above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767